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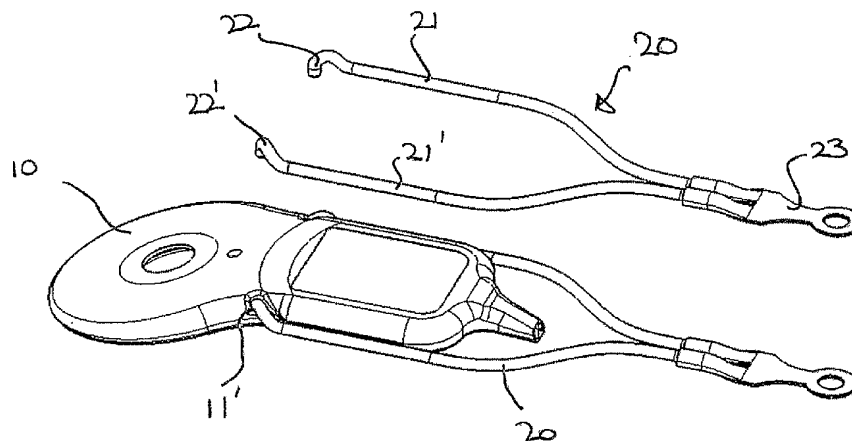
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(54) Title: ARRANGEMENT FOR THE FIXATION OF AN IMPLANTABLE MEDICAL DEVICE



(57) Abstract: A medical implant, such as a cochlear implant, comprising a fixating point which is located remotely from the medical implant. This arrangement can reduce the risk of post operative infection in a patient in which the medical implant is implanted.

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**ARRANGEMENT FOR THE FIXATION OF AN IMPLANTABLE
MEDICAL DEVICE**

Field of the Invention

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This invention relates to the fixation of implantable medical devices such as a cochlear implant, within a patient.

Priority

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This application claims priority from Australian Provisional Patent Application No. 2005906228 filed on 10 November 2005. The entire content of this application is hereby incorporated by reference.

15 **Background of the Invention**

Medical implants are used in many areas of medicine to enhance the length and/or quality of the life of the implant recipient. Such implants include pacemakers, controlled drug delivery implants and cochlear implants.

20

The insertion of such devices often requires surgery, and once in place, it is desirable to not have to replace the device, or if occasional replacement is necessary, the number of replacement procedures should be kept to a minimum.

25

One major factor in determining whether a patient must undergo surgery again is the secure fixation of the device within the patient. If the device has not been securely fixed in position, it may be necessary to repeat the procedure.

An improperly fixed device can result in less than optimal performance of the device, as well as severe medical consequences for the patient.

5 It is particularly important to have the device properly fixed in the early post operative stage, before fibrous tissue and bone has formed around the device to assist in its retention.

10 The fixation of the implantable device often takes a significant proportion of the time of the surgery, and often necessitates the area around the implant site to be completely open, increasing the severity and risks of the surgery.

15 It is preferred to perform minimally invasive procedures to minimise the severity and risk of the surgery. One such procedure involves the use of a periosteal pocket, where a smaller incision is made, and the device is slid into the formed pocket between the bone and the tissue.

20 However, some types of medical implants do not lend themselves to this type of procedure. One such device is a cochlear implant, which is used to treat patients who suffer from hearing loss.

A cochlear implant allows for electrical stimulating signals to be applied directly to the auditory nerve fibres of the patient, allowing the brain to perceive a hearing sensation approximating the natural hearing sensation. These stimulating signals are applied by an array of electrodes implanted into
25 the patient's cochlear.

The electrode array is connected to a stimulator unit which generates the electrical signals for delivery to the electrode array. The stimulator unit in turn is operationally connected to a signal processing unit which also contains

a microphone for receiving audio signals from the environment, and for processing these signals to generate control signals for the stimulator.

5 The signal processing unit is in practice, located externally to the patient and the stimulator is implanted within the patient, usually near the mastoid on the patient's skull and underneath the surrounding tissue. The processor and stimulator may communicate by various wireless means including by a radio frequency link.

10 The implant procedure commonly involves removing some of the bone to form a well for receiving the stimulator to assist in the security of the fixation. Additional fixation is commonly used and is achieved using sutures or biocompatible screws.

15 Thus, fixating cochlear implants has traditionally required that the site of fixation be completely open to allow full and unrestricted access to the site. This requires a large opening to be formed, increasing the complexity of and the risk associated with the surgery as well as increasing the recovery time of the patient.

20 It is therefore an object of the present invention to provide a means of facilitating the fixation of a medical implant in a patient.

Summary of the Invention

25 According to a first aspect of the present invention, there is provided a medical implant for implanting in a patient, the medical implant having a fixating point for fixating the medical implant to the patient, wherein the fixating point is disposed remotely from the medical implant.

In one form, the fixating point is provided on a fixating connector, connecting the fixating point to the medical implant.

- 5 In another form, the fixating connector is removably attachable to the medical implant.

In one form, the distance between the fixating point and the medical implant is variable.

10

In one form, the fixating connector is conformable.

In one form, the medical implant is a cochlear implant.

- 15 Optionally, the fixating connector at least partially houses at least a portion of a lead supporting an array of electrodes extending from the cochlear implant.

- According to a second aspect of the invention, there is provided a fixating connector having a fixating point for fixating the fixating connector to a
20 patient, and at least one connecting point for connecting the fixating connector to an implantable medical device.

In one form, the fixating connector is conformable.

- 25 In one form, the medical implant is a cochlear implant.

In one form, the fixating connector is able to act as a docking station for the medical implant.

According to a third aspect of the present invention, there is provided a medical implant having at least one connecting point for connection to a fixating connector according to the second aspect of the present invention. Preferably, the medical implant is a cochlear implant.

5

According to a fourth aspect of the present invention, there is provided a cochlear implant having a lead supporting an electrode array extending therefrom, the cochlear implant having an extension for at least partially housing at least a portion of the lead.

10

Optionally, the extension is removably attachable to the cochlear implant.

According to a fifth aspect of the present invention, there is provided a medical implant for implanting in a patient, the medical implant having at least one protrusion extending therefrom, for insertion into bone of the patient to thereby fixate the medical implant to the patient.

15

In one form, the at least one protrusion is angled so as to allow movement of the medical implant in one direction, but to impede movement in the opposite direction.

20

In one form, the at least one protrusion is collapsible.

In one form, the medical implant has a plurality of protrusions.

25

According to a sixth aspect of the present invention, there is provided a docking station for a medical implant, the docking station having at least one fixating point for fixating the docking station to a patient, and at least one medical implant engagement means for engaging the medical implant.

In one form, the medical implant is a cochlear implant.

In one form, the at least one engagement means is a clip.

5

Brief Description of the Drawings

The invention will now be described with reference to the following drawings in which:

10

Figure 1 - shows a stimulator and fixation connector according to the present invention;

Figure 2 - shows the arrangement of Figure 1 fixed to a patient's skull;

15

Figure 3 - shows an alternative form of fixing the arrangement of Figure 1 to the patient's skull;

Figure 4 - shows an alternative form of the arrangement of Figure 1;

20

Figure 5 - shows a further alternative form of the arrangement of Figure 1;

Figure 6 - shows yet a further alternative form of the arrangement of Figure 1;

25 Figure 7 - shows yet a further alternative form of the arrangement of Figure 1;

Figure 8 - shows yet a further alternative form of the arrangement of Figure 1;

Figures 9A to 9C - are close up views of various forms of connection adjusting means;

Figure 10A - is a plan view of a portion of a stimulator that is modified to be
5 used with the present invention;

Figure 10B - is a side view of the stimulator of Figure 10A;

Figure 11 - is a cross-sectional view of the stimulator of Figure 10B;
10

Figure 12 - is a cross-sectional view of an alternative of the arrangement of Figure 11;

Figure 13 - shows an alternative form of the fixation connector according to
15 the present invention;

Figure 14 - shows the fixator connector of Figure 13 in use;

Figure 15 - shows a further modification of the fixation connector shown in
20 Figure 13, being used as a docking station;

Figure 16 - is a top view of the fixation connector of Figure 15;

Figure 17 - shows the fixation connector of Figures 15 and 16 in use;
25

Figure 18 - shows a securing arrangement according to a different aspect of the present invention;

Figure 19 - shows an alternative to the arrangement of Figure 18;

Figure 20 – shows a further alternative to the arrangement of Figure 18;

Figure 21 – shows a fixating connector according to a third aspect of the
5 present invention;

Figure 22 – shows a bottom view of the fixating connector of Figure 21, in use;

Figure 23 – shows a cross-sectional profile of the fixating connector of Figure
10 21; and

Figure 24 – shows a cross-sectional profile of an alternative arrangement of
the fixating connector of Figure 21.

15 Detailed Description of the Preferred Embodiment

Figure 1 shows an arrangement according to one aspect of the present
invention. Illustrated is a fixation connector 20 provided in this case by a
bracket having a fixating point 23 and two arms 21 and 21' terminating in
20 hooks 22 and 22' respectively.

Figure 1 also shows how bracket 20 connects to medical implant 10 (in this
case, the stimulator unit of a cochlear implant). Stimulator unit 10 has holes
11(not visible in Figure 1) and 11' for receiving respective hooks 22 and 22' of
25 the bracket 20. This provides a secure connection to bracket 20.

Stimulator unit 10 may be constructed such that its hermetically sealed casing
may be extended to allow more space to provide receiving holes 11 and 11'.
Alternatively, flanges may be added to provide location points.

According to an aspect of the present invention, the fixating point 23 of bracket 20 is located away from the stimulator unit 10. This allows stimulator 10 to be effectively fixated to the patient's skull by fixating the bracket 20 at the fixating point 23. It will be appreciated that the stimulator unit 10 can therefore be fixated without having to have access to the area around the stimulator unit 10. The fixation may be accomplished by simply fixating the bracket 20 at a single point and may be done via a much smaller incision.

Bracket 20 may be made from any suitable biocompatible material such as stainless steel, titanium, ceramic or polymeric material, or a combination of these materials as would be understood by the person skilled in the art. It will be appreciated that the choice of a suitable rigid material allows for the bracket to also form a handle with which to steer the implant into position, for example into a periosteal pocket.

Where the stimulator unit 10 is low in profile, bracket 20 enables fixation of the device without the need to drill the skull as is currently often required. This is particularly advantageous for patients with thin skulls such as infants. In these cases, drilling of the skull often results in complete removal of the bone down to the dura mater.

Nevertheless, bracket 20 is also removable to allow the stimulator unit 20 to be used in a more traditional procedure where a well may need to be formed in the skull and the bracket may not be needed and/or may be in the way. Removal may be before implantation or after placement of the implant, in which case the steering feature of the bracket can still be used.

Alternatively, if a well is used, the arms 21 of bracket 20 may be bent or conformed to accommodate the vertical displacement of the stimulator unit 10.

- 5 It will be appreciated that the invention also provides for flexibility in that it is applicable to, and allows, a range of different surgical techniques and is not limited to the particular ones described herein.

An illustration of the arrangement being put in place on the skull of a patient is shown in Figure 2, in which a portion of the skull 30 is exposed by incision 10 50 and the stimulator unit 10 is slid between the skull 30 and scalp tissue 31 in a periosteal pocket.

The provision of bracket 20 allows the stimulator unit 10 to be pushed into the pocket and can also act as a handle to guide and place the stimulator unit 10 15 into a desired position, in the periosteal pocket. Once stimulator unit 10 is properly located, it can be fixated in place by fixating bracket 20 at the fixating point by means of biocompatible bone screw 40. Of course, any other means of fixation may be used as understood by the person skilled in the art. Once affixed, the bracket 20 prevents rotation and translation of the stimulator unit 20 10.

It will be appreciated that this arrangement allows for fixation of the stimulator unit 10 by minimally invasive techniques, thereby reducing the complexity and potential risk of the procedure. Furthermore, by allowing 25 stimulator unit 10 to be placed away from the wound, the risk of postoperative infection is reduced.

The plane of the bone screw 40 may be either lateral as shown in Figure 2, or sagittal, as shown in Figure 3. Arms 21, 21' of bracket 20 may be bent into a

suitable position to allow the bracket 20 to be partially located in a depression or even a hole, such as the mastoid opening 32 as shown in Figure 3. This allows fixation to be done on patients with thin skulls, such as children, which could not properly support a lateral fixation. The scalp tissue 31 of Figure 2
5 has been omitted in Figure 3 for clarity.

Figure 4 shows an alternative shape of bracket 20 with a different connection arrangement with stimulator unit 10. In this arrangement, hooks 22 and 22' are bent downwards so as to be able to be "dropped in" to receiving holes 11 and 11' formed in the casing of stimulator unit 10.
10

Alternatively, the connection between bracket 20 and stimulator unit 10 may be accomplished by providing holes 11 (not visible in this view) and 11' as shown in Figure 5. In this arrangement, hooks 22 and 22' are turned inwards to clasp stimulator unit 10 there between.
15

In yet a further alternative (see Figure 6), bracket 20 may be formed from a flat sheet of material with hooks 22, 22' being in the form of tabs. Arms 21, 21' are twisted so that tabs 22, 22' may be located in corresponding slots 11 (not visible in Figure 6), 11' formed in the casing of stimulator unit 10. The tab/slot connection shown in Figure 6 provides a very robust connection.
20

Figure 7 shows a variation of the arrangement of Figure 6 in which tabs 22, 22' are disposed horizontally and inwardly, to be received in corresponding slots 11(not visible in Figure 7), 11' in the side of stimulator unit 10. This configuration provides for a bracket 20 having a reduced profile.
25

An alternative of this form (or indeed any other form) could equally have protrusions extending from the casing of stimulator unit 10 to be received by corresponding recesses in hooks 22, 22'.

- 5 Figure 8 shows a variation of the arrangement of Figure 7, in which the shank 24 of the bracket 20 may also be offset from the centreline of the stimulator unit to provide a more favourable location point and to reduce the interference with the electrode array (not shown) extending from end 12 of the stimulator unit 10.

10

Figure 9 shows a number of alternative configurations for fixation point 23 of bracket 20. These configurations allow for tailoring of the proximity of the stimulator unit 20 to the location of fixation by providing a plurality of fixating points, which the surgeon can select as the desired fixating point for
15 fixating the stimulator unit 10 to the patient. This effectively allows control over the distance of the stimulator unit 10 to the point of incision. If the surgeon selects a hole closer to the stimulator unit 10, then the excess material can be cut off.

- 20 It is also conceivable that the distance between the location of fixation and the stimulator unit 10 may also be varied by the provision of a plurality of hooks 22, 22' or holes¹ on arms 21, 21', or equally a plurality of holes or protrusions 11, 11' on the stimulator unit 10.

- 25 Figure 10A shows a top view of the stimulator unit 10 casing in which holes 11, 11' have been formed to receive hooks 22, 22' of the bracket 20 respectively. Figure 10B is a side view of the unit in Figure 10A. This shows the casing designed with some excess material to provide a location for the holes.

If the stimulator unit 10 casing is electrically live, it is desirable to insulate the stimulator from the bracket 20. This could be accomplished in a number of ways including making the bracket 20, or at least the hooks 22, 22' from a
5 biocompatible insulating material such as PEEK. Insulation of the stimulator unit 10 is generally accomplished by overmoulding with silicone rubber.

Alternatively, the holes 11, 11' in the stimulator unit casing may be insulated as shown in Figure 11.

10

If the holes are drilled post manufacture, leaving exposed conductive material within the holes, the hooks themselves could just be coated with the insulating material as depicted in Figure 12.

15 The addition of an insulating coating to either the hooks 22, 22' or the holes 11, 11' can also provide an interference fit, thereby enhancing the tightness and robustness of the connection between the two. This can be particularly important if the bracket 20 is used as a handle to force the stimulator unit 10 into a tight periosteal pocket.

20

A further alternative connecting arrangement between the bracket 20 and the stimulator unit 10 has the bracket 20 designed so as to connect with stimulator unit 10 underneath the unit. This configuration is shown in Figure 13, where hooks or pins 22, 22' are turned upwards to be received in corresponding
25 holes in stimulator unit 10 (not shown), disposed underneath the unit. In this view, the bracket 20 also has its shank bent to provide for a sagittal fixation at fixating point 23.

The bracket 20 also has a broader "plate" region 25 on which stimulator unit 10 will rest.

Figure 14 shows the bracket 20 of Figure 13 connected with stimulator unit 10 from underneath, and in place on the patient's skull with connection point 23 being placed to fixate the arrangement sagittally in the patient's mastoid opening 32, underneath the pinna 33 of the outer ear.

Plate 25 (see Figure 13) may be made from a mesh of biocompatible material to reduce the dead space and promote osseo-integration. Furthermore, because the bracket 20 in this configuration is between the stimulator unit 10 and the patient's skull, it could act as a slide to protect the stimulator unit when being inserted.

A further modification of this aspect is to use the bracket 20 as a "docking station" for the implant. Figure 15 shows bracket 20 being used as a docking station for stimulator unit 10. Bracket 20 in this case has been designed so that cradle 25 provides a docking bay with clips 27 and 28 to engage the stimulator unit 10. Of course, any other form of suitable engagement could be used.

20

As shown in Figure 15, bracket 20 can be fixated to the patient's skull 30 as previously described, using bone screw 40 for example, and then stimulator unit 10 can be clipped or otherwise engaged with clips 27 and 28 to securely retain stimulator unit 10 in place.

25

Figure 16 is a top view of bracket 20 of Figure 15, showing clips 27, 27' and 28 for retaining stimulator unit 10 (shown in dotted lines this figure), which will rest in cradle 25 when in place. The configuration shown in Figure 16 is but one of many possible configurations, and may again, be made from any

suitable material or combination of materials. Cradle 25 may also be made of a wire frame to avoid or minimise dead spaces.

Figure 17 shows a bracket 20 designed to act as a docking station fixated onto the patient's skull 30. As previously described, bracket 20 may be fixated to lie within a periosteal pocket under scalp 31. Stimulator unit 10 may then be slid into the pocket and clipped in secure engagement with bracket 20.

Of course it will be appreciated that the concept of the docking station need not be limited to a bracket having an extension for remote fixation of the bracket, and is equally applicable to a docking station that is fixated at the site of the implant.

According to another aspect of the present invention, the stimulator unit 10 could be provided with a series of "teeth" or sharp protrusions 13 on its lower face. These protrusions 13 would engage the bone to prevent or at least impede movement of the stimulator unit 10 once in place. When used in conjunction with bracket 20, the bracket could be used to hold the teeth away from the bone as the stimulator unit 10 is slid into place in its preferred location, and then when properly located, bracket 20 could then be lowered to lower stimulator unit 10 and its teeth into contact with the bone to allow engagement of the teeth with the skull. The teeth 13 could also promote osseointegration.

Even if the stimulator unit 10 is placed with the aid of bracket 20, the existence of the teeth 13 may still impede the insertion of the implant, particularly if the stimulator unit 10 is required to be slid under a periosteal pocket along the mastoid bone. This aspect of the present invention therefore

provides for a number of solutions to this problem as shown in Figures 18, 19 and 20.

5 In Figure 18, the teeth 13 are angled away from the insertion direction to facilitate sliding of the stimulator unit 10 into position. Once in position and teeth 13 have engaged the bone (not shown), the angle of teeth 13 makes it difficult for the stimulator unit 10 to have any anterior movement.

10 In Figure 19, teeth 13 are provided by a series of folding spigots which can fold down into any depression or well drilled into the bone once in place.

Figure 20 is an enhancement of the arrangement of Figure 19 where the spigots have a winged member which engages with a stopper to allow movement in one direction only. In this case, the stimulator unit 10 may be
15 slid into position with spigots lying flat against the unit. If the spigots pass over a well or depression in the bone, it drops down, but is unable to be raised again upon application of anterior movement to the stimulator unit 10.

Conceivably, the bracket 20 as illustrated in and discussed in reference to
20 Figures 13 and 14 could have the plurality of protrusions incorporated underneath plate region 25. This allows standard stimulator units to be able to benefit from this aspect of the invention when used with such a modified bracket 20.

25 According to a further aspect of the present invention, bracket 20 may act as a guide and/or protector of the lead supporting the electrode array extending from stimulator unit 10.

Figure 21 shows a stimulator unit 10 in place on bone 30 with lead 12 extending from stimulator unit 10 and into the mastoid opening 32. Lead 12 passes underneath bracket 20 and out through an opening at its end for feeding into the cochlear.

5

Figure 22 is a bottom view of the arrangement of Figure 21. Shown here is the underneath of stimulator unit 10 connected to bracket 20 as previously described. Within the body of bracket 20 is formed a channel 26 which receives lead 12 along its length, until lead 12 exits bracket 20 and channel 26 at the end.

10

Figure 23 is a cross-section of the arrangement of Figure 22, along the line A-A, shown in location on skull 30. This shows that for at least a part of the length of lead 12, it is enclosed between skull 30 and bracket 20 within channel 26. The material of the bracket 20 may be a biocompatible mesh to again reduce the risk of infection in the space between the skull and the bracket 20.

15

Figure 24 is a cross-section of an alternative configuration of bracket 20, this time formed to provide a channel 26 on the upward side of the bracket, away from skull 30. While not enclosing lead 12 completely, it does provide a guide and lateral protection.

20

The use of this aspect of the invention also reduces the likelihood of migration of the electrode array out of the cochlear.

25

It will be appreciated that this aspect of the invention encompasses a guide or protection member not necessarily provided by a bracket according to the first aspect of the invention. The guide or protecting member may be formed

integral to the stimulator unit 10 or may also be provided as an attachment which does not necessarily also have to provide a fixation function.

5 It will be understood that the above has been described with reference to a particular embodiment and that many variations and modifications may be made to the invention without departing from the scopes of the various aspects of the present invention. For example, the fixating point may be provided as an integral extension of the implant to allow fixation of the implant remote from the implant.

10

It will also be understood that throughout this specification, unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

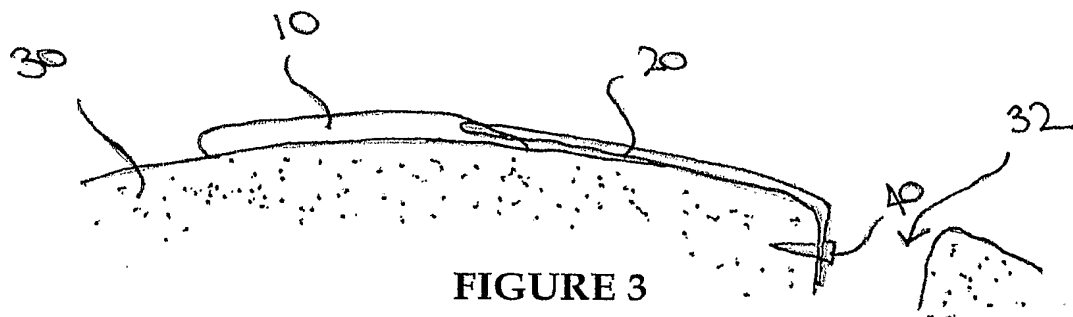
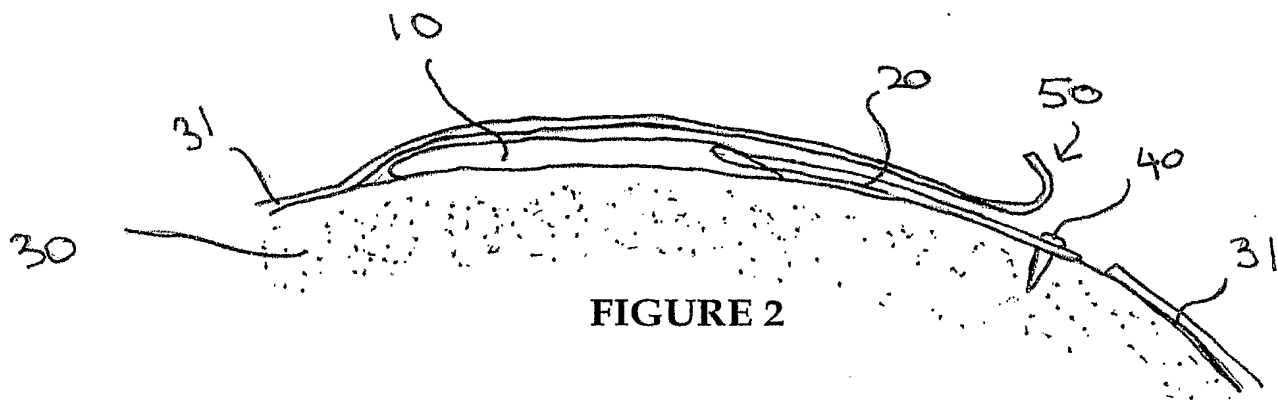
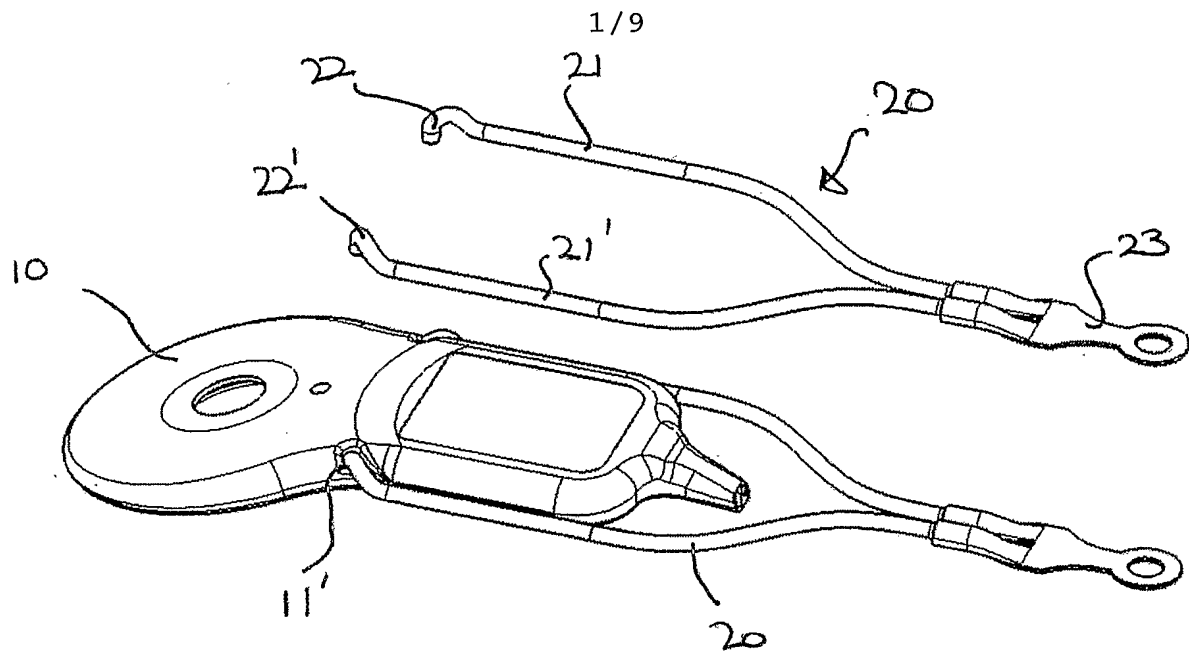
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The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that such prior art forms part of the common general knowledge.

20

CLAIMS:

1. A medical implant for implanting in a patient, the medical implant comprising a fixating point for fixating the medical implant to the patient,
5 wherein the fixating point is disposed remotely from the medical implant.
2. A medical implant as claimed in claim 1 wherein the fixating point is provided on a fixating connector, connecting the fixating point to the medical
10 implant.
3. A medical implant as claimed in claim 2 wherein the fixating connector is removably attachable to the medical implant.
4. A medical implant as claimed in claim 1 wherein the distance between the
15 fixating point and the medical implant is variable.
5. A medical implant as claimed in claim 2 wherein the fixating connector is conformable.
- 20 6. A medical implant as claimed in claim 1 wherein the medical implant is a cochlear implant.



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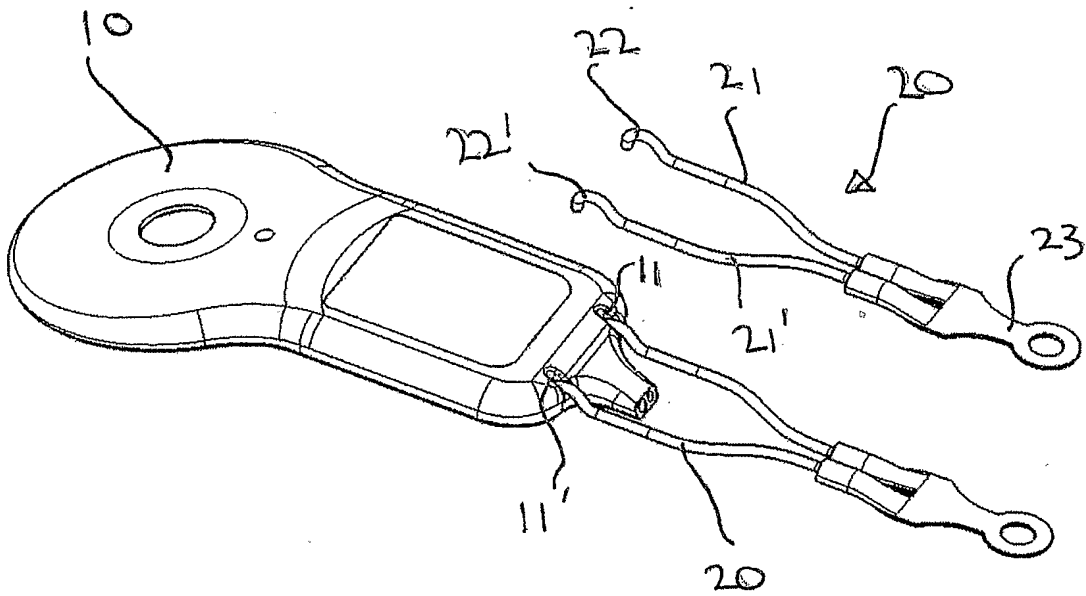


FIGURE 4

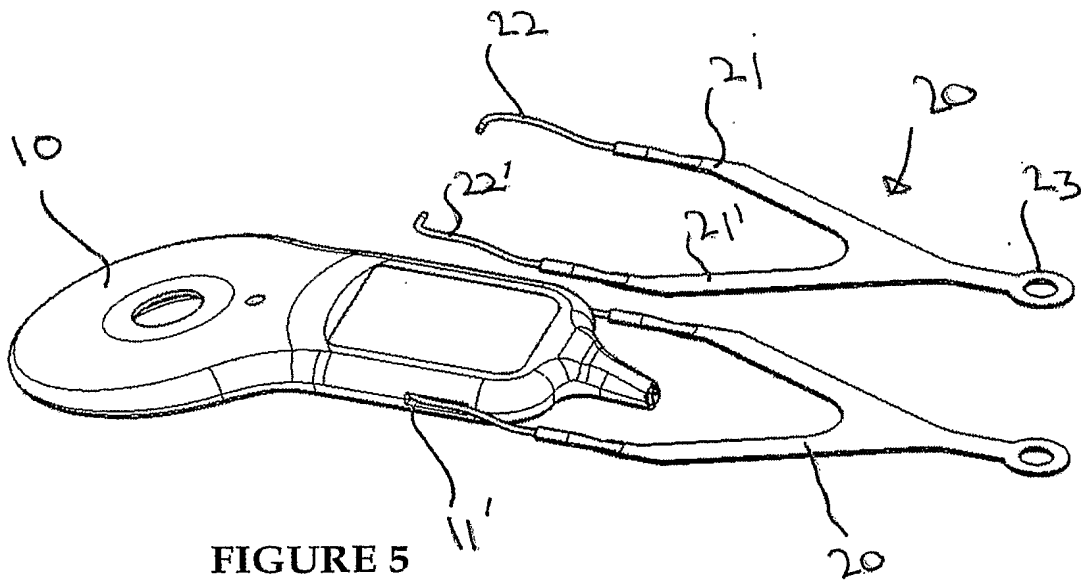
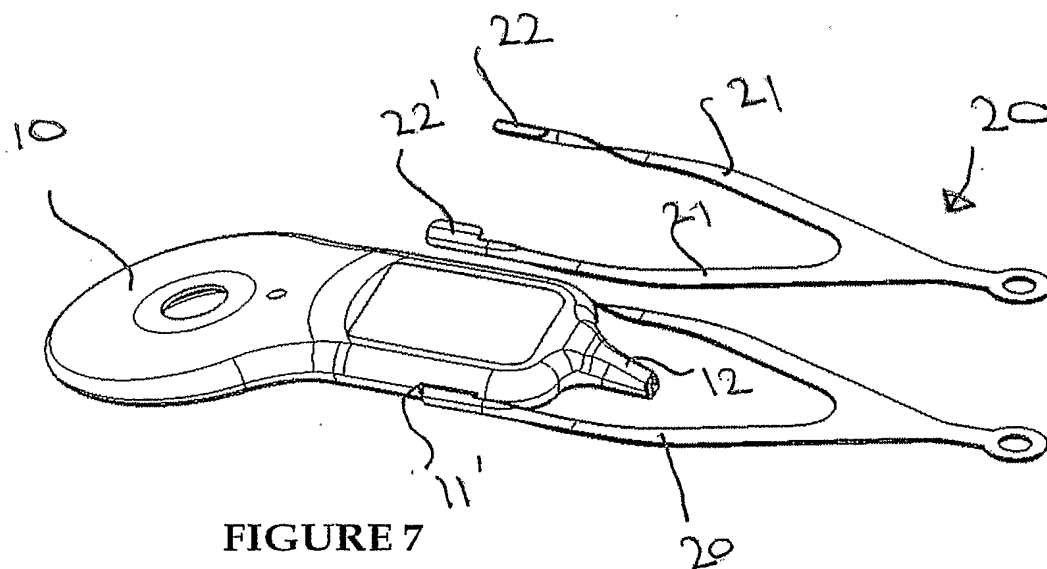
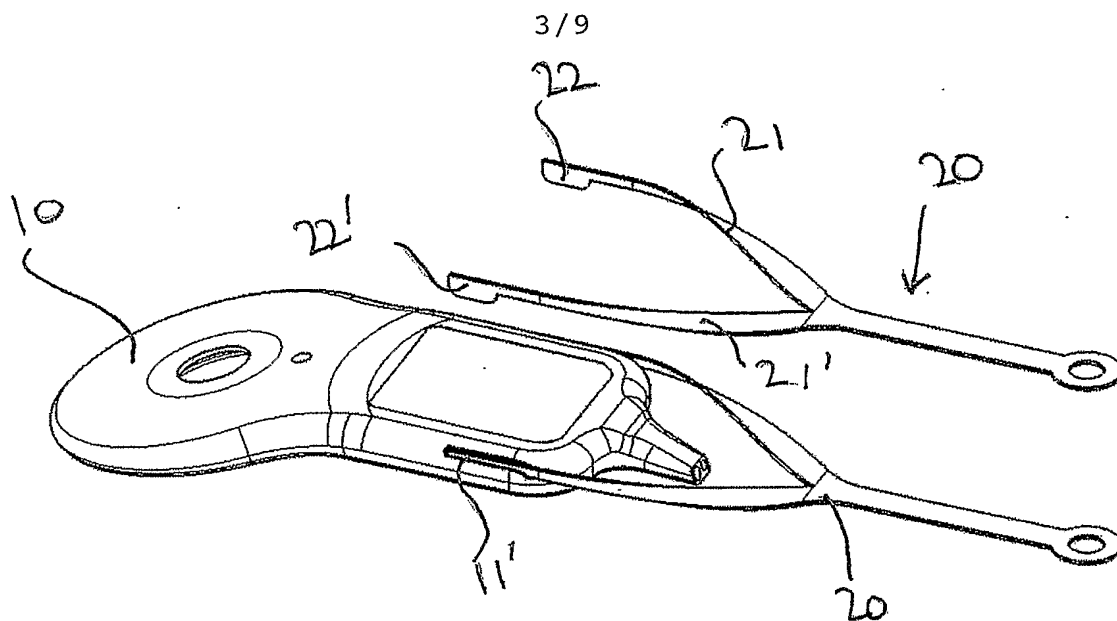


FIGURE 5



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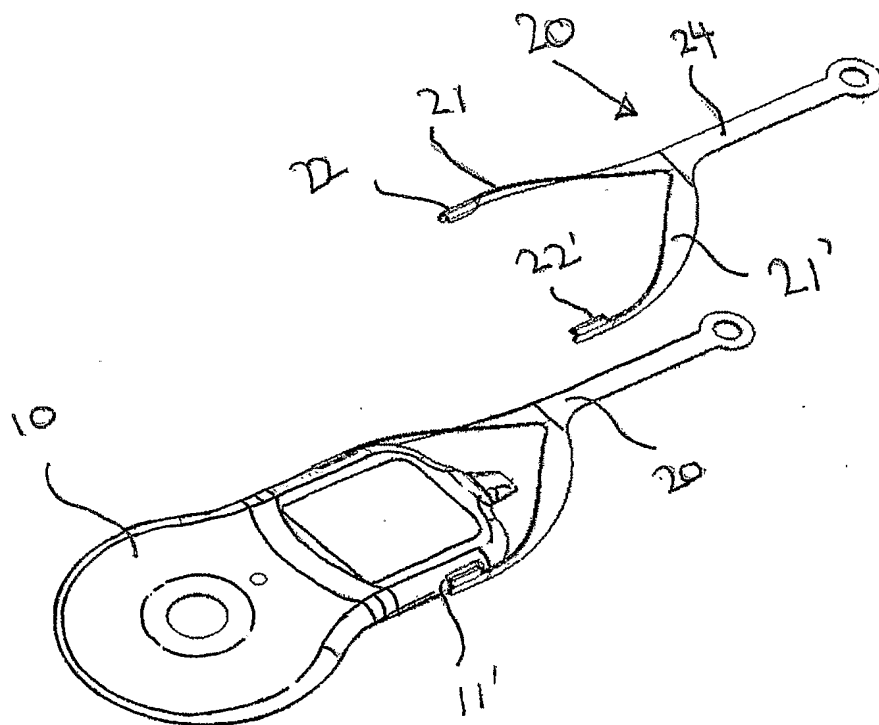


FIGURE 8

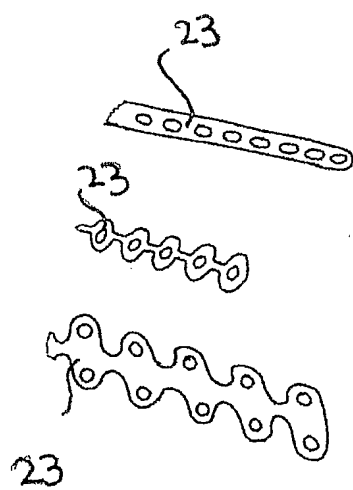


FIGURE 9

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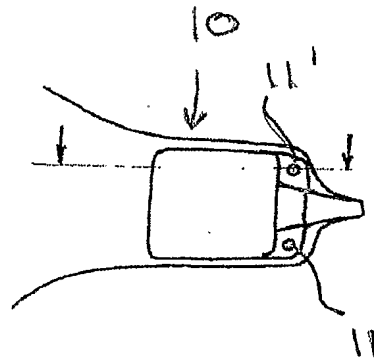


FIGURE 10A



FIGURE 10B

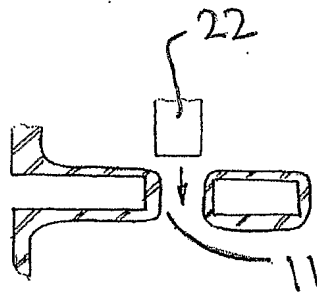


FIGURE 11

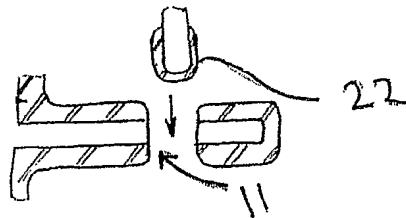


FIGURE 12

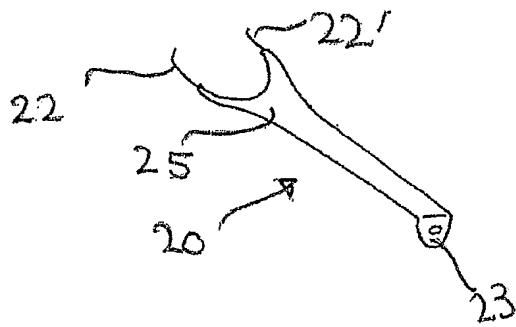


FIGURE 13

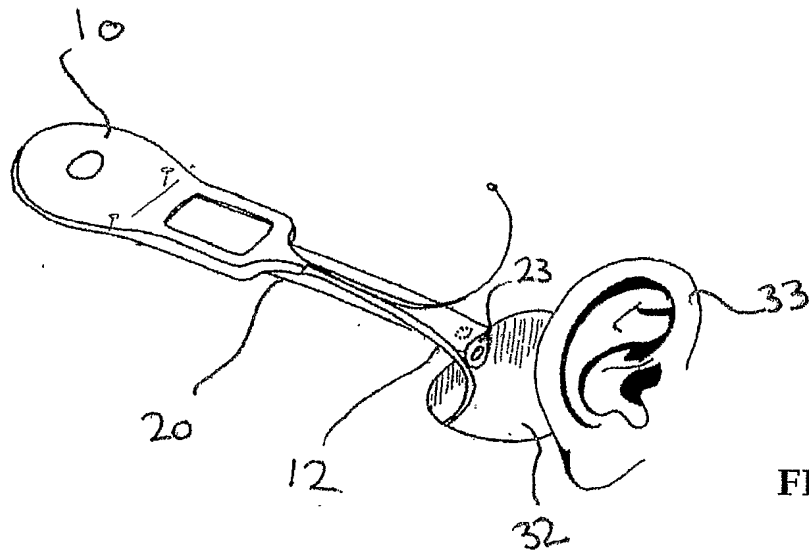


FIGURE 14

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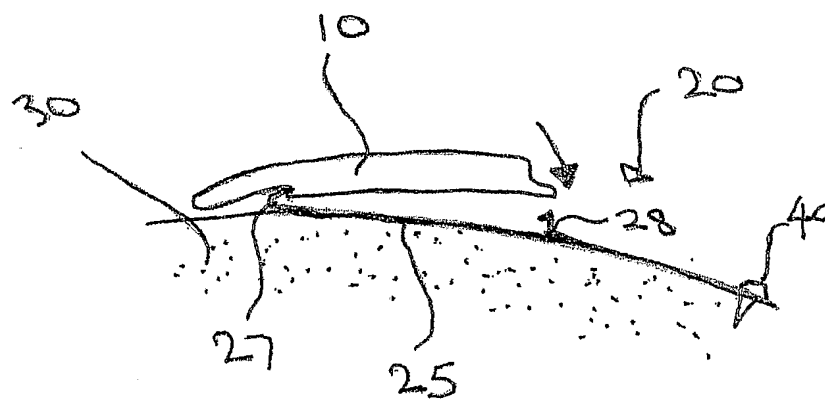


FIGURE 15

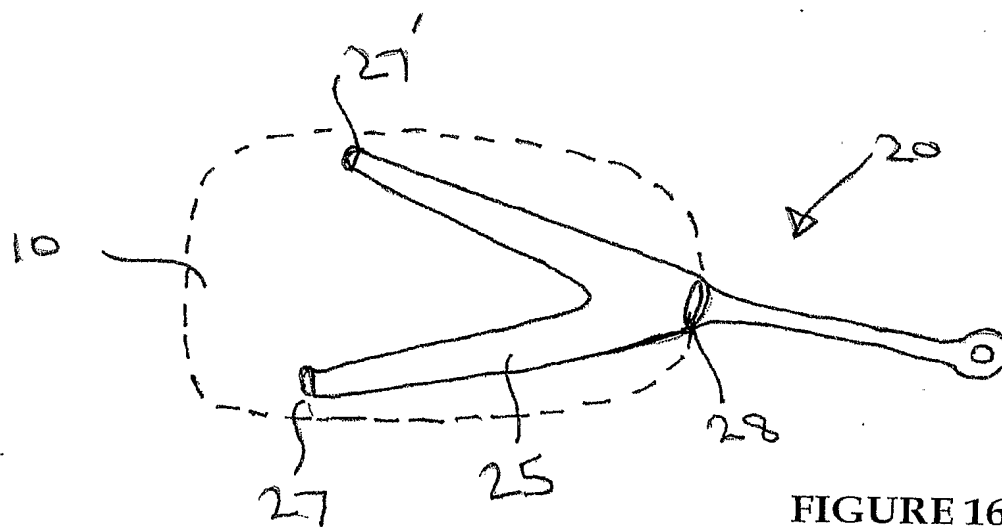
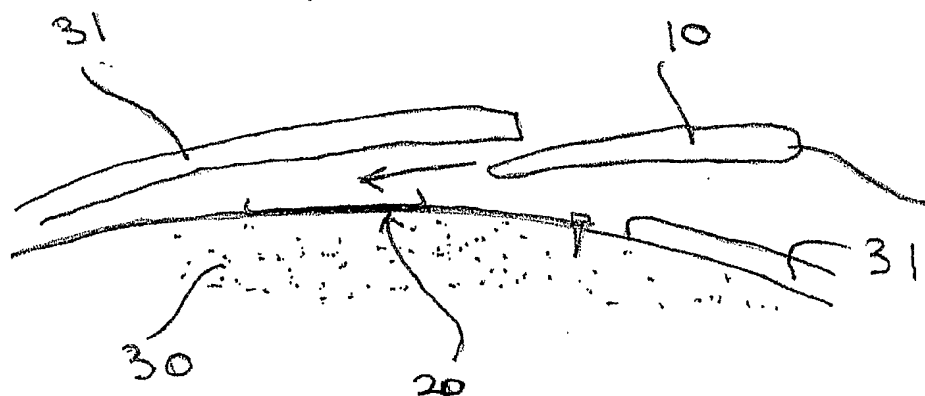


FIGURE 16

FIGURE 17



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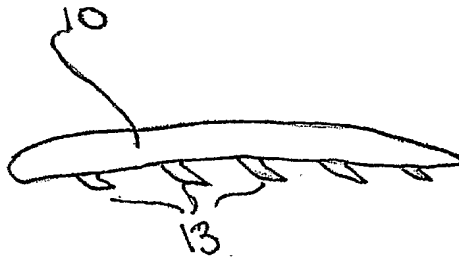


FIGURE 18

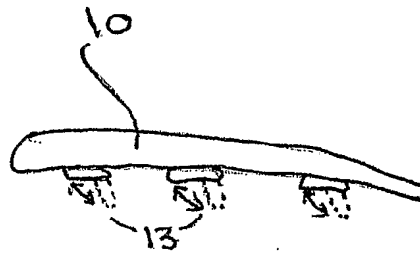


FIGURE 19

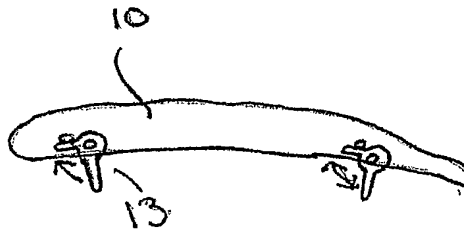


FIGURE 20

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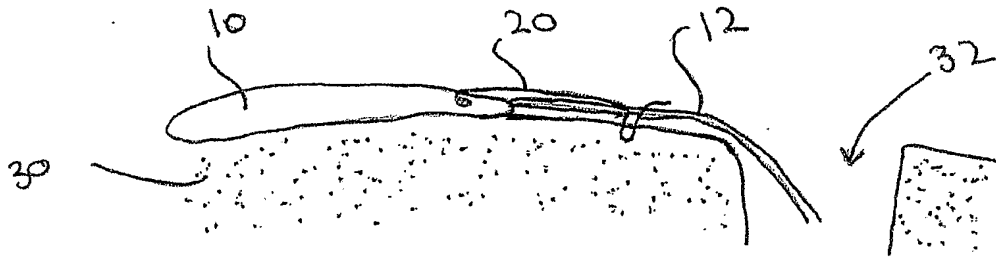


FIGURE 21

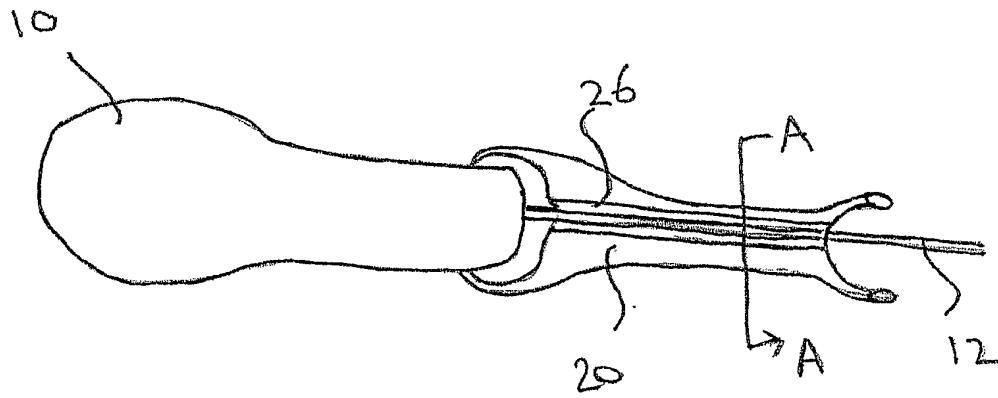


FIGURE 22

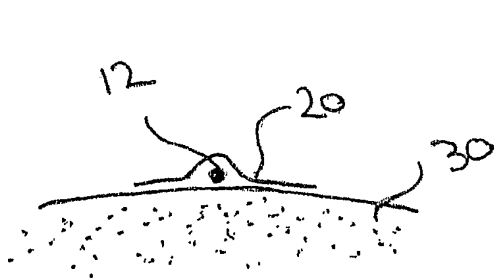


FIGURE 23

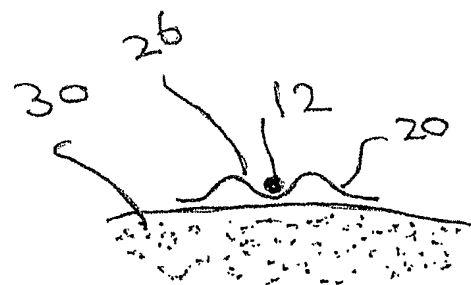


FIGURE 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001632

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61F 2/18 (2006.01) **A61F 11/00** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI: KEYWORDS; A61F/IC OR A61B/IC AND IMPLANT+ AND (TETHER OR CONNECT+ OR +FIX+ OR SECUR+ OR ATTCH+ OR FASTEN+ OR ANCHOR+ OR HOLD+ OR TAG) AND (REMOTE+ OR APART OR DISTAN+ OR SPAC+ OR SEPARAT+) AND (DEVICE OR PACEMAKER OR COCHLEAR OR HOUSING OR CASING OR ENCLOSURE OR BOX)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4986831 A (KING) 22 January 1991 Figure 1, column 5 lines 7 to 28	1, 2
X	WO 2004014269 A (COCHLEAR LIMITED) 19 February 2004 Whole Specification; in particular figures 3 to 6; page 13 line 34 to page 16 line 30	1-6
X	WO 2004014270 A (COCHLEAR LIMITED) 19 February 2004 Whole Specification	1-6

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

* - Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
23 November 2006

Date of mailing of the international search report
01 DEC 2006

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/001632

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E, X	DERWENT ABSTRACT ACCESSION NO. 2006-555721/57, CLASS P32 RU 2282426 A (MIKROB ANTI-PLAGUE RES INST) 27 August 2006 Refer to ABSTRACT	1, 2, 3, 6
X	WO 2003092326 A (COCHLEAR LIMITED) 6 November 2003 Whole Specification	1-6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/001632

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member	
US	4986831	US	5192311		
WO	2004014269	AU	2003249775	US	2006116743
WO	2004014270	AU	2003246464		
WO	03092326	AU	2003227092		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					